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Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

July 1, 2008

TO: CALIFORNIA PHYSICIANS ADMINISTERING JAPANESE ENCEPHALITIS
VIRUS VACCINE INACTIVATED (JE-VAX®)

SUBJECT: CONTINUED USE OF JAPANESE ENCEPHALITIS VIRUS VACCINE
INACTIVATED FROM JULY 1, 2008 – JUNE 30, 2009

SUMMARY

Since July 1, 2006, California law [Health and Safety Code, Section 124172, subdivision (a)] provides that vaccines containing specific levels of mercury cannot be administered to pregnant women and young children, except under certain circumstances. The Secretary of the California Health and Human Services Agency has again granted a 12-month exemption to this restriction for Japanese Encephalitis Virus Vaccine Inactivated (JE-VAX®) from July 1, 2008 to June 30, 2009. This exemption will allow this vaccine to continue to be administered to children younger than three years old and women who are pregnant. The exception was granted because of the dangers posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for residents of California seeking protection against Japanese Encephalitis.

Japanese Encephalitis Disease and Vaccine

Japanese Encephalitis, a mosquito-borne infection, is the leading cause of viral encephalitis (brain infection) in Asia and parts of Oceania. Since 2005, major outbreaks of Japanese Encephalitis have resulted in illness and death of thousands of persons in India and Nepal. Most persons with encephalitis caused by the Japanese Encephalitis virus either die or have residual neurologic disease. Unimmunized children in affected areas are at highest risk of Japanese Encephalitis, while infection during pregnancy may cause miscarriage. There is currently no treatment for Japanese Encephalitis.

The U.S. Food and Drug Administration has licensed only one vaccine against Japanese Encephalitis for use in the United States. The formal name of the vaccine is Japanese Encephalitis Virus Vaccine Inactivated, and its trade name is JE-VAX®. It is manufactured in Japan by the Research Foundation for Microbial Diseases of Osaka University ("BIKEN®") and distributed in the United States by Sanofi Pasteur, Inc.

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Japanese Encephalitis Virus Vaccine Inactivated contains thimerosal as a preservative at a final concentration of 0.007%. The dose for children from 1-<3 years of age is 0.5 milliliters, which contain 17.5 micrograms of mercury. The dose for persons 3 years of age and older is 1.0 milliliters, which contain 35 micrograms of mercury. The mercury content of Japanese Encephalitis Virus Vaccine Inactivated exceeds the limit set by California Health and Safety Code, Section 124172, subdivision (a), of 0.5 micrograms of mercury per 0.5 milliliter dose for vaccines (other than influenza vaccine) administered to young children and pregnant women in California on or after July 1, 2006. The bill which created this law, AB 2943 (Pavley, Chapter 837, Statutes of 2004), was signed by Governor Arnold Schwarzenegger to ensure that pregnant women and children under age three have access to mercury-free vaccines.

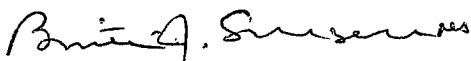
Since 1993, the national Advisory Committee on Immunization Practices has recommended that Japanese Encephalitis Virus Vaccine Inactivated should be offered to persons spending a month or longer in endemic areas during the transmission season, to travelers to areas experiencing epidemic transmission and to persons whose activities, such as extensive outdoor activities in rural areas, place them at high risk for exposure.
(<http://www.cdc.gov/mmwr/preview/mmwrhtml/00020599.htm>.)

Exemption to California Mercury Free Vaccine Act

California Health and Safety Code, Section 124172, subdivision (c), permits the Secretary of the Health and Human Services Agency to exempt the use of a vaccine from Section 124172, subdivision (a) "if the secretary finds, and the Governor concurs, that...shortage of supply of a vaccine that would prevent children under three years of age and knowingly pregnant receiving the needed vaccine," making "necessary the administration of a vaccine containing more mercury than the maximum level set forth in subdivision (a)..." (http://www.leginfo.ca.gov/pub/03-04/bill/asm/ab_2901-2950/ab_2943_bill_20040928_chaptered.html)

The dangers posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for residents of California seeking protection against Japanese Encephalitis virus, an exemption has been granted again from California Health and Safety Code, Section 124172, subdivision (a), for Japanese Encephalitis Virus Vaccine Inactivated for the period of July 1, 2008 through June 30, 2009. This vaccine may continue to be administered, as permitted by other state and federal laws, to children younger than three years old and women who are pregnant. For additional information about this topic, please contact the California Department of Public Health, Immunization Branch, at (510) 620-3737 or www.getimmunizedca.org.

Sincerely,


Mark B Horton, MD, MSPH
Director

cc: CDPH Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators